Rad-57™

Signal Extraction Co-Oximeter™

Service Manual

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The Rad-57™ Co-Oximeter™ Service Manual is intended to provide the necessary information for proper servicing of the Rad-57 Co-Oximetry system. This manual is structured to support troubleshooting to the assembly or module level. This manual does not provide instructions for troubleshooting to the printed circuit board component level. Do not service a Rad-57 unit without completely reading and understanding these instructions. Masimo service training is required prior to utilization of this manual.

CAUTION:

Federal law (U.S.) restricts this device to sale by or on the order of a physician

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Made in USA.

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Covered by one or more of the following U.S. Patents: RE38,492, RE38,476, 6,699,194, 6,684,090, 6,658,276, 6,654,624, 6,650,917, 6,643,530, 6,606,511, 6,584,336, 6,501,975, 6,463,311, 6,430,525, 6,360,114, 6,263,222, 6,236,872, 6,229,856, 6,206,830, 6,157,850, 6,067,462, 6,011,986, 6,002,952, 5,919,134, 5,823,950, 5,769,785, 5,758,644, 5,685,299, 5,632,272, 5,490,505, 5,482,036, international equivalents, or one or more of the patents referenced at www.masimo.com/patents.

Other patents pending.

Table of Contents

Page

1. Overview 1
1.1. About this Manual 1
1.2. WARNINGS, Cautions and Notes 1
2. Testing and Maintenance 2
2.1. Introduction 2
2.2. Cleaning 2
2.3. Battery Operation 3
2.4. Replacing the Batteries 3
2.5. Performance Verification 4
3. Repair 7
3.1. Safety Precautions: 7
3.2. General Procedures 7
3.3. Troubleshooting 7
3.4. Service Messages: 8
4. Repair and Returns 10
4.1. Repair Policy 10
4.2. Return Procedure 10
5. Drawings and Schematics 12

1. Overview

1.1. About this Manual

This manual explains how to service the Rad-57 Co-Oximeter. Important safety information relating to the general use of the Rad-57 appears in the Operator's Manual. Other important safety information is located throughout this manual where appropriate.

1.2. **WARNINGS, Cautions and** Notes

Please read and follow any warnings, cautions and notes presented throughout this manual. An explanation of these labels is as follows:

A **WARNING** is provided when actions may result in a serious outcome (i.e., injury, serious adverse affect, death) to the patient or user. Look for text in a gray shaded box.

Sample of a **WARNING:**

WARNING: THIS IS A SAMPLE OF A WARNING STATEMENT.

A **Caution** is given when any special care is to be exercised by the patient or user to avoid injury to the patient, damage to this device or damage to other property.

Sample of a **Caution:**

Caution: This is a sample of a Caution statement.

A Note is provided when extra general information is applicable.

Sample of a Note:

Note: This is a sample of a Note statement.

2. Testing and Maintenance

2.1. Introduction

2.1.1. This chapter covers; Cleaning, Battery Operation and Replacement, Testing and how to obtain service under normal operation.

Note: No internal adjustments or recalibration is required.

2.1.2. Service should be done by qualified personnel only. Safety checks should be performed in accordance with local and governmental regulations.

2.2. Cleaning

WARNING: BEFORE CLEANING THE CO-OXIMETER, TURN THE UNIT OFF.

2.2.1. To clean the display panel, use a cotton swab moistened with 70% isopropyl alcohol and gently wipe the panel.

2.2.2. To clean the outer surface of the instrument, use a soft cloth moistened with a 70% isopropyl alcohol.

WARNING: DO NOT ALLOW LIQUIDS TO ENTER THE INTERIOR OF THE INSTRUMENT.

2.2.3. To decontaminate unit, refer to Section 4.2.2.

Cautions:

- **Do not autoclave, pressure sterilize, or gas sterilize this oximeter.**
- **Do not soak or immerse the monitor in any liquid.**
- **Use the cleaning solution sparingly. Allow unit to air dry. Excessive solution can flow into the monitor and cause damage to internal components.**
- **Do not touch, press, or rub the display panels with abrasive cleaning compounds, instruments, brushes, rough-surface materials, or bring them into contact with anything that could scratch the panel.**
- **Do not use petroleum-based or acetone solutions, or other harsh solvents, to clean the oximeter. These substances attack the device's materials and device failure can result.**

2.3. Battery Operation

2.3.1. The Rad-57 includes (4) AA alkaline batteries.

2.3.2. Before using the Rad-57 as a handheld or transport monitor, it is best to verify the charge level of the batteries. Please reference the Operator's Manual for specifications of battery life.

2.3.3. The battery charge LED indicators on the keypad will indicate the approximate life left with the batteries.

2.3.4. As a precaution against memory effects, it is advisable to replace the batteries as soon as the final indicator starts flashing.

2.4. Replacing the Batteries

2.4.1. Turn the unit off and remove the patient cable connection.

2.4.2. Position the unit face down (use a soft surface to protect the unit from possible cosmetic damage).

2.4.3. Depress the battery cover release button and slide the cover off.

2.4.4. Remove the (4) depleted batteries. Install the (4) replacement batteries into the battery compartment paying attention to proper polarity positioning.

2.4.5. Depress the battery cover release button and slide the cover back onto the unit. Verify the button pops up securing the cover.

2.4.6. As soon as the batteries are installed the unit will automatically turn on. Verify all LEDs illuminate momentarily, that all four battery charge LEDs remain lit, and that the unit stabilizes to its normal operation mode.

Caution: Follow local governing guidelines for proper disposal of internal batteries. Do not incinerate.

2.5. Performance Verification

Caution: The limits for SpCO will remain set ("Sticky") even during a power cycle. SpO2 limits will reset to the factory default after a power cycle.

2.5.1. To test the performance of the Rad-57 Co-Oximeter after repairs or during routine maintenance, follow the procedure outlined in this section starting at step 2.6. If the oximeter fails any of the tests, discontinue its use and correct the problem before returning the unit back to the user.

Note: Before testing, verify the batteries are fully charged. Disconnect any patient cables or sensors.

2.5.2. Power-On Self-Test

2.5.2.1. While the unit is off, depress the Power/Standby button and verify the unit turns on, that all LED indicators illuminate momentarily and the speaker makes a beep sound. Depress and hold (~ 2 sec) the power button again and verify the unit turns off.

2.5.3. Key Press Button Test

2.5.3.1. With the unit on, press each soft key button (with the exception of the Power/Standby button), and verify that the oximeter acknowledges each key-press with an audible beep tone and/or by indicating an associated change on the display.

2.5.4. Menu Navigation Test

2.5.4.1. With the unit turned on, press the MODE-ENTER button several times slowly and verify the menu scrolls through the various top level menu selections:

2.5.4.1.1. Level 1: Alarm volume "AL VOL".

2.5.4.1.2. Level 2: Alarm limits "90/LO".

2.5.4.1.3. Level 3: Averaging and Sensitivity "SEN Nor".

2.5.4.1.4. Level 4: Led brightness, Line frequency and Factory defaults "888/888".

2.5.4.1.5. Level 5: Trend settings "Tnd OFF"

2.5.4.1.6. Press the button a sixth time. Menu should return to the beginning view.

2.5.4.2. Press MODE-ENTER button twice (should be at the 90/LO selection). Verify the up and down arrows change the hi and low parameters.

2.5.5. Display Contrast Test

2.5.5.1. With the unit turned on, depress the MODE-ENTER button (4) four times. When the display appears as 888/888, use the up and down arrows to verify the contrast both brightens and dims accordingly.

2.5.6. Testing with Masimo Set Tester (SpO2 only)

2.5.6.1. (Currently, there is no Masimo Tester to simulate an SpCO condition. However, it is possible to test the alarm capability of the unit by placing a sensor on a test subject. By setting the High limit of SpCO to 10% (factory default), it is generally understood that most healthy individuals will fall far below this range and should not induce an alarm. Subsequently, setting the SpCO to a value of 1% will most likely cause an alarm event.)

2.5.6.2. Connect the Masimo Set Tester to the Patient connecter.

2.5.6.3. Verify a reading appears within 15 seconds. The display should show numeric values of 80% – 84% for SpO2 and 60 – 63 for the BPM.

2.5.6.4. Test the alarm limits at each of the following settings:

2.5.6.5. Verify that at each **alarm-inducing** setting the unit initiates an audible alarm and a visual alarm (a red LED and the parameter number should be flashing). Verify the yellow "Alarm Silenced" LED is off during the alarm condition.

Test 1 (Unit should **not** alarm)

Limits	% SpO_2
High	90
Low	75

Test 2 **(Unit should alarm)**

Limits	%SpO2
High	**80**
Low	75

Test 3 (Unit should **not** alarm)

Limits	BPM
High	70
Low	55

Test 4 **(Unit should alarm)**

Limits	BPM
High	**60**
Low	55

2.5.6.6. Press the Alarm Silence button once and verify the alarm is silenced and the yellow “Alarm Silenced” LED is flashing.

2.5.6.7. Wait 120 seconds and verify that the alarm silence times out and the audible alarm is activated again and the yellow LED turns off.

2.5.6.8. To disable Alarm mute, press the Alarm button once and verify an audible alarm is heard.

2.5.6.9. Press the up and down arrows while the unit is actively measuring vitals. Verify an increase and/or decrease in pulse volume. Continue pressing the down arrow to verify the pulse beep can be silenced.

2.5.7. Battery Test

2.5.7.1. Install four (4) “AA” alkaline batteries. Verify the unit turns on immediately after installation.

2.5.7.2. Turn the unit off, then on again.

2.5.7.3. If the unit was installed with brand new batteries, all four (4) battery charge LED indicators should be illuminated indicating a full charge.

2.5.7.4. If all four (4) LEDs are not lit, then remove all four (4) batteries and try another set. Repeat steps 4.7.2 and 4.7.3.

2.5.7.5. If all four (4) indicators are still not lit, contact Masimo Corporation using the information in Section 4.2.11 to request an RMA to return the unit for repair.

3. Repair

3.1. Safety Precautions:

WARNING: DO NOT DISASSEMBLE OR ASSEMBLE THE UNIT WHILE THE BATTERIES ARE STILL INSTALLED.

WARNING: ENSURE THE UNIT HAS BEEN PROPERLY CLEANED PER THE CLEANING INSTRUCTIONS.

3.2. General Procedures

3.2.1. Examine the unit prior to disassembly or troubleshooting and inspect for cosmetic damage. External damage may be helpful in determining the root cause of the failure.

3.2.2. Note any markings or labeling the end user may have placed on the unit that may need to be duplicated or transferred in the event the housing or ancillary components are to be replaced.

3.2.3. Make note of the unit serial number.

3.2.4. Make note of the software versions in the event the Co-Oximeter board or system board is replaced, as these boards require software updates to make them compatible with the end user's version of software.

3.2.5. Contact Masimo Corporation using the information in Section 4.2.11 to research the warranty history of the unit to determine if the unit will be covered under warranty.

3.3. Troubleshooting

3.3.1. The troubleshooting procedures in this manual instructs the technician to isolate the failure down to the sub-assembly level. The intention is to have the Unit Under Test (UUT) repaired with minimal steps. The Masimo Set Tester is needed to perform the Performance Verification in Section 2.5 upon completion of repairs.

3.3.2. Tools required are as follows:

Phillips head screwdriver #0
Multimeter

3.3.3. The troubleshooting steps below are presented in order of the most probable cause first. Proceed to the next step only if the unit continues to fail.

3.3.4. Always note the software versions of boards prior to repair.

3.3.5. After units have been repaired, the Perfomance Verification Section 2.5 must be performed.

3.4. Service Messages:

Upon detection of a system error, the main software alerts the user with an audible alarm indicator and displays the appropriate error code on the Handheld's main display. The MX board is held in reset and no other runtime functions are available to the user until the Handheld is put through a power cycle or until power is completely removed and re-applied to the system (removal and replacement of batteries).

System Error	System Error Code
MX Board Failure	1
MX Board Communication Failure	2
5V Voltage Supply Out of Range	3
Red Voltage Supply Out of Range	4
Blue Voltage Supply Out of Range	5
Battery Drop Voltage Out of Range	6
Battery Voltage Out of Range	7

Symptom	Cause and Corrective Action Steps
• **Speaker Alarming (very loud) and unit is not functioning or displaying.**	• **Probable Watchdog error.** 1. Replace System Board.
• **Alarm LED does not Illuminate** 1. Unit is in an alarm state and an audible alarm can be heard.	1. Replace Keypad. 2. Replace System Board.
• **Alarm Condition But No Audible Indication.** 1. Unit is in an alarm state.	1. Replace Speaker. 2. Replace System Board.
• **Alarm Silence LED not illuminated.** 1. Unit is in a non-monitoring state. No alarm indicated.	1. Replace Keypad. 2. Replace System Board.
• **Display Missing Segments**	1. Replace Display. 2. Replace System Board.
• **Button Function Error** 1. Pressing one or more buttons will not activate the menu selection.	1. Replace Keypad. 2. Replace System Board.
• **"No Sen" Message** 1. Cable is connected with sensor attached.	1. Replace sensor. 2. Replace patient cable. 3. Replace co-oximeter board.
• **"No CbL" Message (Rad-57)** 1. Cable is connected.	1. Replace cable and/or sensor. 2. Replace co-oximeter board.
• **No SpCO LED** 1. SpCO cable connected.	1. Replace cable. 2. Replace Keypad. 3. Replace co-oximeter board.
• **Unit Will Not Turn Off**	1. Replace Keypad. 2. Replace System Board.

If unable to repair unit, then please call (800)326-4890 option #2 to arrange for return to Masimo Corporation.

4. Repair and Returns

4.1. Repair Policy

4.1.1. Masimo or an authorized Service Department must perform warranty repair and service. Do not use malfunctioning equipment. The product must be repaired.

4.1.2. Please clean contaminated/dirty equipment before returning. Make sure it is fully dry before packing the equipment.

4.1.3. To return the Rad-57 unit for service, please follow the Return Procedure outlined in this section.

4.2. Return Procedure

4.2.1. Please clean contaminated/dirty equipment before returning and make sure it is completely dry before packing the equipment.

4.2.2. Recommended decontamination procedure for the Rad-57 instrument that has the potential for being exposed to blood or other potentially infectious materials.

4.2.2.1. Put on Lab coat or other protective garment.

4.2.2.2. Put on gloves.

4.2.2.3. Place equipment on the designated decontamination table.

4.2.2.4. Apply cleaning agent to paper towel or use Cidex wipes.

4.2.2.5. Wipe down all aspects of the equipment.

4.2.2.6. Let the equipment air dry completely.

4.2.2.7. Remove gloves.

4.2.2.8. Move equipment to the area designated for equipment that has been through the decontamination process.

4.2.2.9. Dispose of all contaminated products properly.

4.2.3. Package the equipment securely – in the original shipping container if possible – and enclose the following information and items:

4.2.4. Call Masimo “domestically” at (800)326-4890, option #2, “internationally” at 949-297-7498, option #2 and ask for an RMA number.

4.2.5. A letter or email describing in detail any symptoms or difficulties experienced with the pulse oximeter. Please include the RMA number in the letter.

4.2.6. Warranty information – a copy of the invoice or other applicable documentation must be included.

4.2.7. Purchase order number to cover repair if the oximeter is not under warranty, or for tracking purposes if the warranty is in effect.

4.2.8. Ship-to and bill-to information.

4.2.9. Person (name, telephone/Telex/fax number, email and country) to contact for any questions about the repairs.

4.2.10. A document stating the co-oximeter has been decontaminated for bloodborne pathogens.

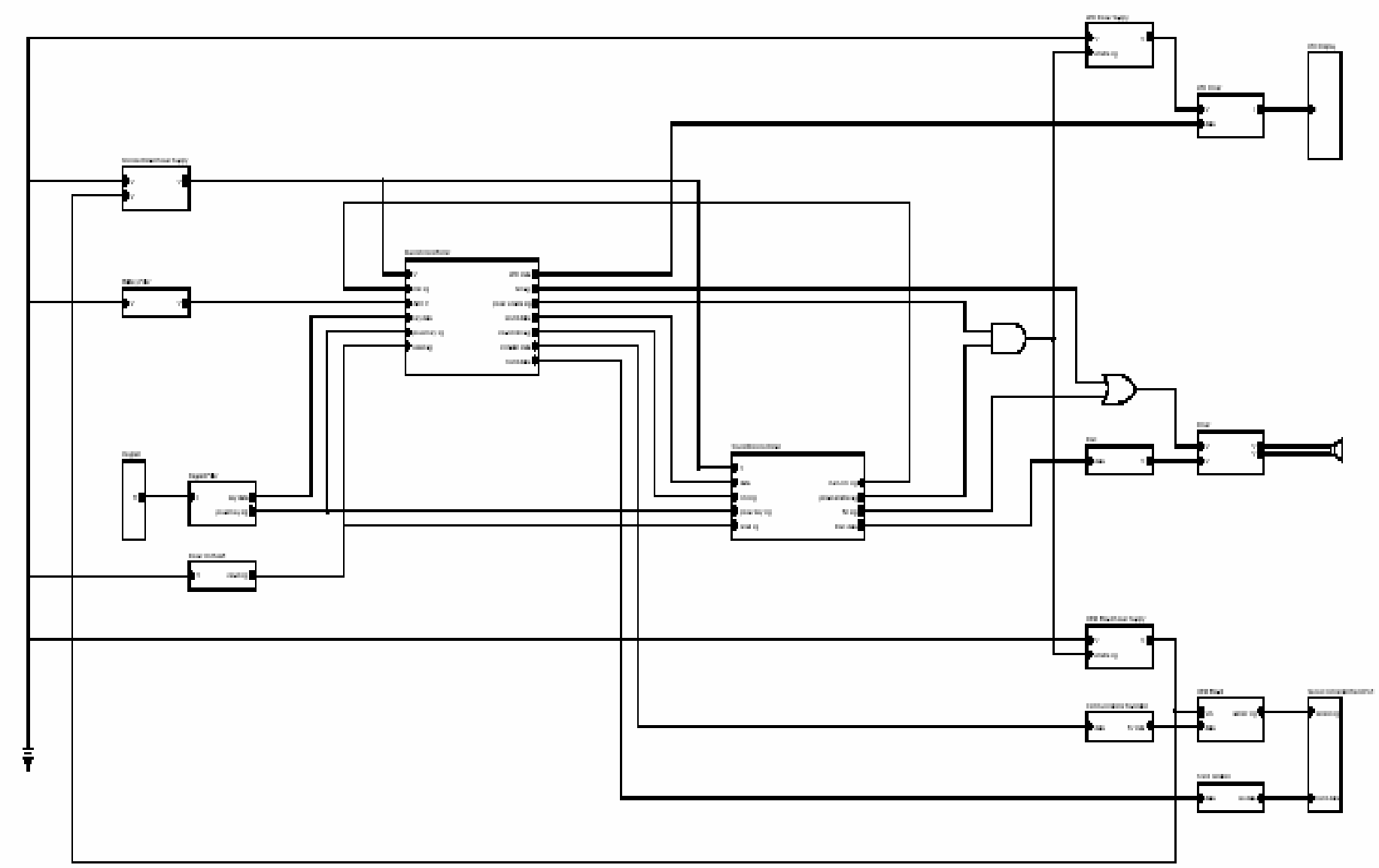
4.2.11. Return the co-oximeter to the following shipping address:

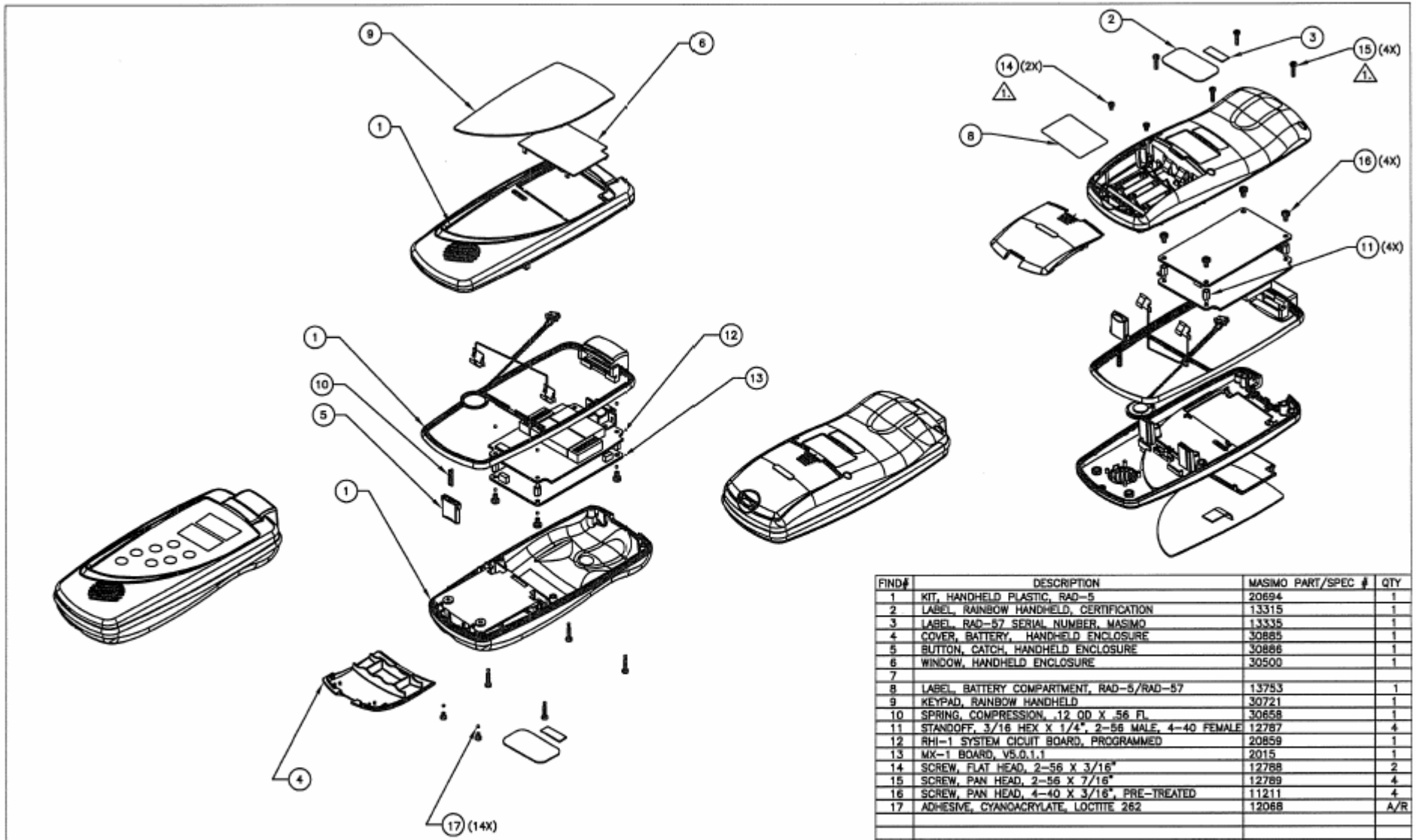
Masimo Corporation
40 Parker
Irvine, California
USA 92618

(Domestic Toll Free): 800-326-4890, option #2
(International): 949-297-7498, option #2
FAX: 949-297-7499

13918/UM10030A-0406

5. Drawings and Schematics





FIND#	DESCRIPTION	MASIMO PART/SPEC #	QTY
1	KIT, HANDHELD PLASTIC, RAD-5	20694	1
2	LABEL, RAINBOW HANDHELD, CERTIFICATION	13315	1
3	LABEL, RAD-57 SERIAL NUMBER, MASIMO	13335	1
4	COVER, BATTERY, HANDHELD ENCLOSURE	30885	1
5	BUTTON, CATCH, HANDHELD ENCLOSURE	30886	1
6	WINDOW, HANDHELD ENCLOSURE	30500	1
7			
8	LABEL, BATTERY COMPARTMENT, RAD-5/RAD-57	13753	1
9	KEYPAD, RAINBOW HANDHELD	30721	1
10	SPRING, COMPRESSION, .12 OD X .56 FL	30658	1
11	STANDOFF, 3/16 HEX X 1/4", 2-56 MALE, 4-40 FEMALE	12787	4
12	RHI-1 SYSTEM CICUIT BOARD, PROGRAMMED	20859	1
13	MX-1 BOARD, V5.0.1.1	2015	1
14	SCREW, FLAT HEAD, 2-56 X 3/16"	12788	2
15	SCREW, PAN HEAD, 2-56 X 7/16"	12789	4
16	SCREW, PAN HEAD, 4-40 X 3/16", PRE-TREATED	11211	4
17	ADHESIVE, CYANOACRYLATE, LOCTITE 262	12068	A/R

NOTES: UNLESS OTHERWISE SPECIFIED

1. APPLY ADHESIVE (17) TO SCREWS PRIOR TO SECURING THE SCREWS.

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MATERIAL: N/A

FINISH: N/A

TOLERANCE (EXCEPT AS NOTED)
.X = ±.1
.XX = ±.01
.XXX = ±.005
ANG = ±1°

DIMENSIONS ARE IN INCHES UNLESS OTHERWISE SPECIFIED

THIRD ANGLE PROJECTION

DO NOT SCALE DWG

DR/REV: J. SCHMIDT	8/1/05	
CHK:		
ENG:		
MFG:		
QA:		

MASIMO

PART TO BE LISTED ON LC REEL: NO

TITLE: ASSEMBLY, RAINBOW HANDHELD INSTRUMENT I

SIZE: C | SCALE: NONE | DOC NO: R-DR-20659 | REV: D

D-DRG: R-DRO-12235 | DRG DATE: 8/1/05

DATE: 9/8/04 | SHEET: 1 OF 4

REV	DRO #	DATE	REVISION DESCRIPTION	ENGINEER
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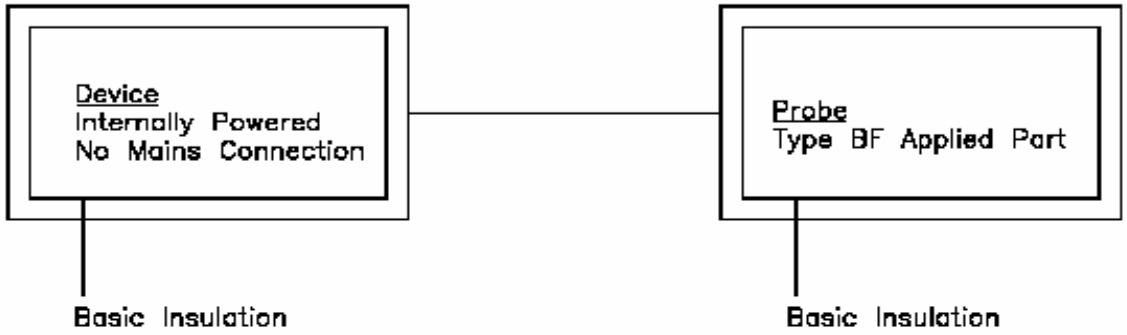

NOTES:

1. Basic Insulation =
   1.5kVAC HI POT
   4mm Creepage Distance
   2.5mm Air Clearance
2. Classification: Internally Powered Equipment
   Operation: Continuous Operation
   Applied Part: Type BF

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.XX = ±.01
.XXX = ±.005
XXX = ±1°
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ENG:		
MFG:		
QA:		

THIRD ANGLE PROJECTION

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PART IS LISTED IN UL FILE: NO

TITLE: RHI-1 ISOLATION BLOCK DIAGRAM

SIZE: A | DWG NO: R-DR-60019 | REVISION: A

SCALE: NONE | SHEET: 1 OF 1